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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,749

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David Angelo Tomasso

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27777 7590 02/26/2008  
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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,749	<b>Applicant(s)</b> TOMASSO ET AL.	
	<b>Examiner</b> NATALIA LEVKOVICH	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendments and remarks dated 11/20/2007 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 112***

3. Claims 1 and 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to the amended claim 1, absent a specific structure of the test element, it is still unclear what structural features of the test element recess would ensure that the test element' can be acted upon by the liquid dispense or aspirating station, while the test element is in the recess'. The 'test element recess 'for holding one or more...test element holders', remains unclear, in light of the specification, defining the test element holder as a 'recess for holding the test elements' (see [0042]).

### ***Claim Rejections - 35 USC § 102***

4. Claims 1, 3-6, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Clark et al. (US 6190617).

With respect to claims 1, 3-4, 6, 10-11 and 13, Clark discloses an automated analyzer comprising, as shown in Figure 4A, concentrically arranged carousels 36, 32 ['transport system', 'first and second rotors'] and stationary probe 6 ['liquid dispense or aspirating station']. The carousels carry various types of 'removable holders', such as a test sample container segment assembly of Figure 36 having recesses 606 ['test element recesses', probe tip dispensers'] configured for holding sample containers 620 of Figure 39 ['fluid supply sections for holding a sample', 'sample reservoirs', or 'test elements'] and capable of holding probe tips. The holders arrange the above mentioned items on the 'same line of travel' intersecting the stationary probe. The system also includes 'measurement devices', such as modules 69, 71 and photomultiplier tube which measure the chemiluminescent signal of the samples (Figures 16 and 17). As to the size of the analyzer, Clark discloses "compact, table-top analyzers" in column 2, lines 57-58.

Referring to claim 5, Clark teaches that "the reaction vessel containing the test sample and one or more reagents is transferred to a process carousel wherein controlled environment conditions exist ['incubator' – Ex]" (Col.16, lines 5-10).

Regarding claim 11, the test sample container segment assembly of Clark can contain a number of sample containers [ 'different test elements'].

***Allowable Subject Matter***

5. Claims 7-9, 12 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach, or fairly suggest waste collection containers and centrifuge modules located on the rotors, as recited in claims 7-9.

The prior art does not teach, or fairly suggest a first holder including dry-slide test elements and a second holder including an immunoassay test reaction container, as recited in claim 12, or a test element holder containing cup-shaped wells and test strips, as recited in claim.

### ***Double Patenting***

6. Claims 1 and 3-14 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 24-26 of co-pending Application No 10/436,537. See the appropriate paragraphs of the 06/21/2007 Office Action.

### ***Response to Arguments***

7. Applicant's arguments dated 11/20/2007 have been fully considered but they are not persuasive, or moot in view of the new grounds of rejection.

Applicant argues that 'Clark fails to anticipate or render obvious the claimed invention', because 'there is no teaching or suggestion of a probe tip dispenser or test element recess as part of the removable holder in addition to the fluid supply section as

claimed. Moreover, there is no teaching or suggestion of having such features in the same line of travel'. Examiner disagrees. As was discussed above, Figure 36 of Clark shows recesses 606 ['test element recesses', probe tip dispensers'] configured for holding sample containers 620 of Figure 39 ['fluid supply sections for holding a sample', 'sample reservoirs', or 'test elements'] and capable of holding probe tips. The recesses 606 are arranged such, that, when the holders are placed on the rotor, the recesses would be on the 'same line of travel'.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill A. Warden/

Supervisory Patent Examiner, Art Unit 1797